

UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Guiting Lin, Y. Joseph Mo, Mingqi Lu, Yinglu Guo

Application No.: 10/803,460 Filed Date: 03/18/2004

Confirmation No. 5541 Group: 1614 Examiner: Not Assigned

For: Neuronal Growth Enhancement by Prostaglandin Compositions and Methods

CERTIFICATE OF MAILING	
I Hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
on <u>11/5/04</u>	<u>Lynn F. McMiller</u>
Date	Signature
<u>Lynn F. McMiller</u>	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(More than 3 months after receipt of the International Search Report, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

- ☐ Copies of the cited references are enclosed.
- ☐ In accordance with 37 C.F.R. § 1.98 (d), copies of cited references (\*list reference not enclosed\*) are not enclosed as these references were entered in earlier application, U.S. Application No. [ ], to which the present application claims priority under 35 U.S.C. 120. The earlier application contains copies of the cited references.
- ☒ If copies of references AA – AK, AA2 – AF2 would benefit the Examiner of this case, the Examiner is invited to call the undersigned attorney and copies will be forwarded immediately.
- ☒ Listed references AB, AM, AZ, AC2, AU2, AZ4 were cited in the enclosed International Search Report in a counterpart foreign application.

Concise Explanation Requirement (non-English references):

- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
  - ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ the enclosed English language abstract.

☐ Applicant requests that the following pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], Publication No. [ ], Publication Date [ ],  
by [inventor(s)], filed [ ], Docket No.: [ ]

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Examiner

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Date

☐ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:


☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account No. 50-1935 in the amount of \$[ ]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account No. 50-1935.

Respectfully submitted,

BOWDITCH & DEWEY, LLP

By   
Roger P. Zimmerman  
Date: November 5, 2004  
Registration No. 38,670  
Direct tel.: (508) 416-2433  
Telephone: (508) 879-5700  
Facsimile: (508) 929-3073

Bowditch & Dewey, LLP  
161 Worcester Road  
P.O. Box 9320  
Framingham, Massachusetts 01701-9320



PTO-1449 REPRODUCED				ATTORNEY DOCKET NO.		APPLICATION NO.	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION 11/03/2004 (Use several sheets if necessary)				301888-3009-101		10/803,460	
				APPLICANT NexMed (Holdings), Inc.			
				FILING DATE 03/18/2004		GROUP ART UNIT 1614	
U.S. PATENT DOCUMENTS							
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,127,118	28 Nov 1978	Latorre	128	79	
	AB	4,596,242	24 Jun 1986	Fischell	128	79	
	AC	4,801,587	31 Jan 1989	Voss, et al.	514	248	
	AD	4,861,764	29 Aug 1989	Samour, et al.	514	177	
	AE	4,980,378	25 Dec 1990	Wong, et al.	514	785	
	AF	5,082,866	21 Jan 1992	Wong, et al.	514	785	
	AG	5,256,652	26 Oct 1993	El-Rashidy	514	58	
	AH	6,007,824	28 Dec 1999	Duckett, et al.	424	195.1	
	AI	6,046,244	4 Apr 2000	Buyuktimkin, et al.	514	785	
	AJ	6,117,949	12 Sep 2000	Rathi, et al.	525	415	
	AK	6,118,020	12 Sep 2000	Buyuktimkin, et al.	560	155	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	WO 95/09590	13 Apr 1995	PCT			
	AM	WO 2004/022064	18 Mar 2004	PCT			
	AN						
	AO						
	AP						
	AQ						
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR	Aoki, J., et al., "Signal Transduction Pathway Regulating Prostaglandin EP3 Receptor-Induced Neurite Retraction: Requirement for Two Different Tyrosine Kinases," <i>Biochem J</i> , 340:365-369 (1999).					
	AS	Bakircioglu, M., et al., "The Effect of Adeno-Associated Virus Mediated Brain Derived Neurotrophic Factor in an Animal Model of Neurogenic Impotence," <i>J Urol</i> , 165:2103-2109, (2001).					
	AT	Benson, G., "Erectile Response to Transurethral Alprostadil and Prazosin," <i>J Urol</i> , 159:1527-1528 (1998).					
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	AA 2	6,224,573	1 May 2001	Yeager, et al.	604	181				
	AB 2	6,274,159	14 Aug 2001	Marotta, et al.	424	426				
	AC 2	6,323,241	27 Nov 2001	Yeager, et al.	514	573				
	AD 2	6,414,028	2 Jul 2002	Buyuktimkin, et al.	514	573				
	AE 2	6,486,207	26 Nov 2002	Yeager, et al.	514	573				
FOREIGN PATENT DOCUMENTS										
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)										
	AU	Bukkapatnam, R., and Pow-Sang, J., "Radical Prostatectomy in the Management of Clinically Localized Prostate Cancer," <i>Canc Cont</i> , 8(6): 496-502 (2001).								
	AV	Burnett, A., "Strategies to Promote Recovery of Cavernous Nerve Function After Radical Protatectomy," (2002). (From <i>Springer-Verlag Abstracts</i> , 2002, Abstract No. 10.1007/s00345-002-0303-2).								
	AW	Catalona, W., and Bigg, S., "Nerve-Sparing Radical Prostatectomy: Evaluation of Results After 250 Patients," <i>J Urol</i> , 143: 538-544.								
	AX	Choi, S., <i>et al.</i> , "Potentiation of PGE2-mediated cAMP Production During Neuronal Differentiation of Human Neuroblastoma SK-N-BE(2)C Cells," <i>J Neurochem</i> , 79:303-310 (2001).								
	AY	Coleman, R., <i>et al.</i> , "International Union of Pharmacology Classification of Prostanoid Receptors: Properties, Distribution, and Structure of the Receptors and Their Subtypes," <i>Pharm Rev</i> , 46(2): 205-229 (1994).								
	AZ	Costabile, R., <i>et al.</i> , "Efficacy and Safety of Transurethral Alprostadil in Patients with Erectile Dysfunction Following Radical Prostatectomy," <i>J Urol</i> , 160:1325-1328 (1998).								
	AR 2	Damon, D., "NGF-independent Survival of Postganglionic Sympathetic Neurons in Neuronal-vascular Smooth Muscle Cocultures," <i>Am J Physiol Heart Circ Physiol</i> , 280: H1722-H1728 (2001).								
	AS2	DeChaves, E., <i>et al.</i> , "Inhibition of Neurite Growth by Ceramide in Rat Sympathetic Neurons," <i>Ann NY Acad Sci</i> , p.405 (1998).								
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	AF2	2004/0001872	1 Jan 2004	Shih, et al.	424	426	
FOREIGN PATENT DOCUMENTS							
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	AT 2	Diaz-Flores, L., <i>et al.</i> , "Intense Vascular Sprouting From Rat Femoral Vein Induced by Prostaglandins E1 and E2," <i>Anat Rec</i> , 238: 68-76 (1994).					
	AU 2	Emilien, G., "Alprox-TD," <i>CPNS Inv Drugs</i> , 2(3): 311-320, (2000).					
	AV 2	<i>The Encyclopedia of Molecular Biology</i> , Kendrew, J., <i>et al.</i> , eds. (Oxford: Blackwell Sciences), (1994).					
	AW 2	Englehardt, P.F., <i>et al.</i> , "Comparison of Intraurethral Liposomal and Intracavernosal Prostaglandin-E1 in the Management of Erectile Dysfunction," <i>Brit J of Urol</i> , 81:441-444 (1998).					
	AX 2	Fukushige, T., <i>et al.</i> , "Establishment and Characterization of a Cell Line of Congenital Primitive Neuroectodermal Tumor of Soft Tissue," <i>Cell Pathol</i> 62:159-166 (1992).					
	AY 2	Furmanski, P., <i>et al.</i> , "Expression of Differentiated Functions in Mouse Neuroblastoma Mediated by Dibutyl-cyclic Adenosine Monophosphate," <i>Nature</i> 233:413-415 (1971).					
	AZ 2	Gurwitz, D., and Cunningham, D., "Thrombin Modulates and Reverses Neuroblastoma Neurite Outgrowth," <i>Proc Natl Acad Sci USA</i> , 85:3440-3444 (1988).					
	AR 3	Hiruma, H., <i>et al.</i> , "Prostaglandin E2 Enhances Axonal Transport and Neuritogenesis in Cultured Mouse Dorsal Root Ganglion Neurons," <i>Neuroscience</i> , 100(4): 885-891 (2000).					
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	AS3	Honn, K., <i>et al.</i> , "Effects of Prostaglandins Possessing an $\alpha$ , $\beta$ -Unsaturated Carbonyl on Tumor Growth and Differentiation," In <i>Advances in Prostaglandin, Thromboxane, and Leukotriene Research</i> , vol. 15, Hayaishi, O., and Yamamoto, S., eds., (NY: Raven Press), pp. 411-413 (1985).					
	AT3	Karabulut, A., <i>et al.</i> , "Objective Penile Vascular Response to Intraurethral Prostaglandin E2 (Dinoprostone)," <i>Urol Int</i> , 67:160-162 (2001).					
	AU3	Kirtland, S., "Prostaglandin E1: A Review," <i>Prost Leuko Ess Fat Acids Rev</i> , 32: 165-174 (1988).					
	AV3	Lazo, J., and Ruddon, R., "Neurite Extension and Malignancy of Neuroblastoma Cells After Treatment With Prostaglandin E1 and Papaverine," <i>J Natl Cancer Inst</i> , 59(1): 137-143 (1977).					
	AW3	Liebermann, D., and Sachs, L., "Nuclear Control of Neurite Induction in Neuroblastoma Cells," <i>Exp Cell Res</i> , 113: 383-390 (1978).					
	AX3	Jin, K., <i>et al.</i> , "Vascular Endothelial Growth Factor (VEGF) Stimulates Neurogenesis <i>in vitro</i> and <i>in vivo</i> ," <i>PNAS</i> , 99(18) 11946-11950 (2002).					
	AY3	Magee, T., <i>et al.</i> , "Gene Therapy of Erectile Dysfunction in the Rat with Penile Neuronal Nitric Oxide Synthase," <i>Biol Repro</i> , 67:20-28 (2002).					
	AZ3	<i>Martindale, The Extra Pharmacopia</i> , Reynolds, J., ed. (London: The Pharmaceutical Press), p.1353 (1982).					
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	AR 4	"Non-Newtonian Fluid," In <i>McGraw-Hill Encyclopedia of Physics</i> , Parker, S. ed., (McGraw-Hill), pp.856-858 (1993).					
	AS4	<i>The Merck Index</i> , Budavari, S., et al., eds., (NJ: Merck & Co.), pp.1352-1354 (1996).					
	AT 4	Montorsi, F., et al., "Recovery of Spontaneous Erectile Function After Nerve-Sparing Radical Retropubic Prostatectomy With and Without Early Intracavernous Injections of Alprostadil: Results of a Prospective, Randomized Trial," <i>J Urol</i> , 158: 1408-1410, (1997).					
	AU 4	Moreland, R., et al., "The Biochemical and Neurologic Basis for the Treatment of Male Erectile Dysfunction," <i>J Pharm Exp Ther</i> , 296(2): 225-234 (2001).					
	AV 4	Narumiya, S., and FitzGerald, G., "Genetic and Pharmacological Analysis of Prostanoid Receptor Function," <i>J Clin Inv</i> , 108(1): 25-30, (2001).					
	AW 4	Narumiya, S., et al., "Prostanoid Receptors: Structures, Properties, and Functions," <i>Physio Rev</i> , 79(4): 1193-1226 (1999).					
	AX 4	Nehra, A., et al., "Rationale for Combination Therapy of Intraurethral Prostaglandin E1 and Sildenafil in the Salvage of Erectile Dysfunction Patients Desiring Noninvasive Therapy," <i>Intl J Imp Res</i> , 14(I) S38-S42 (2002).					
	AY 4	Novak, T., et al., "Management of Erectile Dysfunction Following Radical Prostatectomy," In <i>Current Clinical Urology, Male Sexual Function: A Guide to Clinical Management</i> , Mulcahy, J. ed., (NJ: Humana Press), pp. 109-123					
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	AZ 4	Padma-Nathan, H., "A New Era in the Treatment of Erectile Dysfunction," <i>Am J Cardiol</i> , 84:18N-23N, (1999).					
	AR 5	Padma-Nathan, H., <i>et al.</i> , "Treatment of Men with Erectile Dysfunction with Transurethral Alprostadil," <i>N Engl J Med</i> , 336:1-7 (1997).					
	AS5	Peterson, C.A., <i>et al.</i> , "Erectile Response to Transurethral Alprostadil, Prazosin, and Alprostadil-Prazosin Combinations," <i>J Urol</i> , 159:1523-1528, (1998).					
	AT 5	Porst, H., "Transurethral Alprostadil with MUSE (medicated urethral system for erection) vs Intracavernous Alprostadil - a Comparative Study in 103 Patients with Erectile Dysfunction," <i>Int J Impot Res</i> , 9:187-192 (1997).					
	AU 5	Prasad, K., <i>et al.</i> , "Modification of the Expression of Adenosine 3',5'-Cyclic Monophosphate-Induced Differentiated Functions in Neuroblastoma Cells by Beta-Carotene and D-Alpha-Tocopheryl Succinate," <i>J Amer Col Nut</i> , 13(3):298-303 (1994).					
	AV 5	Prasad, K., "Morphological Differentiation Induced by Prostaglandin in Mouse Neuroblastoma Cells in Culture," <i>Nature New Bio</i> , 236:49-52 (1972).					
	AW 5	Prasad, K., "Neuroblastoma Clones: Prostaglandin Versus Dibutyl Cyclic AMP, 8-Benzylthio-cyclic AMP, Phosphodiesterase Inhibitors and X-Rays," <i>PSEBM</i> , 140:126-129 (1972).					
	AX 5	Prasad, K., and Kumar, S., "Role of Cyclic AMP in Differentiation of Human Neuroblastoma Cells in Culture," <i>Cancer</i> 36:1338-1343 (1975).					
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	AY 5	Quinlan, D., <i>et al.</i> , "Sexual Function Following Radical Prostatectomy: Influence of Preservation of Neurovascular Bundles," <i>J Urol</i> , 145:998-1002 (1991).					
	AZ 5	Rajfer, J., "Growth Factors and Gene Therapy for Erectile Dysfunction," <i>Rev Urol</i> , 2(1):34 (2000).					
	AR 6	Rehman, J., and Melman, A., "Normal Anatomy and Physiology," In <i>Current Clinical Urology, Male Sexual Function: A Guide to Clinical Management</i> , Mulcahy, J., ed., (NJ: Interpharm Press), pp. 1-46 (2001).					
	AS6	Satoh, T., <i>et al.</i> , "CNS-Specific Prostacyclin Ligands as Neuronal Survival-Promoting Factors in the Brain," <i>Euro J Neuro</i> , 11:3115-3124 (1999).					
	AT 6	Satoh, T., <i>et al.</i> , "Designed Cyclopentenone Prostaglandin Derivatives as Neurite Outgrowth-Promoting Compounds for CAD Cells, a Rat Catecholaminergic Neuronal Cell Line of the Central Nervous System," <i>Neuro Letters</i> , 291:167-170, (2000).					
	AU 6	Satoh, T. <i>et al.</i> , "Neurotrophic Actions of Novel Compounds Designed From Cyclopentenone Prostaglandins," <i>J Neurochem</i> , 77:50-62 (2001).					
	AV 6	Satoh, T., <i>et al.</i> , "Prostaglandin J2 and its Metabolites Promote Neurite Outgrowth Induced by Nerve Growth Factor in PC12 Cells," <i>Biochem Biophys Res Comm</i> , 258:50-53 (1999).					
	AW 6	Schirar, A., <i>et al.</i> , "A Large Proportion of Pelvic Neurons Innervating the Corpora Cavemosa of the Rat Penis Exhibit NADPH-Diaphorase Activity," <i>Cell Tissue Res</i> , 278(3): 517-525 (1994). (Springer Link Abstract).					
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	AX 6	Shafik, A., <i>et al.</i> , "Magnetic Stimulation of the Cavemous Nerve for the Treatment of Erectile Dysfunction in Humans," <i>Intl J Impot Res</i> , 12(3): 137-141, (2000). (From Nature.com abstracts, Abstract No. 3900521a).					
	AY 6	Sharlip, I.D., "Does Natural Erectile Function Improve Following Intracavernous Injections of Vasoactive Drugs?," <i>Intl J Impot Res</i> , 9:193-196 (1997).					
	AZ 6	Slawin, K., <i>et al.</i> , "Sural Nerve Interposition Grafting During Radical Prostatectomy," <i>Rev Urol</i> , 4(1): 17-23 (2002).					
	AR 7	Sondell, M., <i>et al.</i> , "Vascular Endothelial Growth Factor Has Neurotrophic Activity and Stimulates Axonal Outgrowth, Enhancing Cell Survival and Schwann Cell Proliferation in the Peripheral Nervous System," <i>J Neurosci</i> , 19(14):5731-5740 (1999).					
	AS7	Straus, D., and Glass, C., "Cyclopentenone Prostaglandins: New Insights on Biological Activities and Cellular Targets," <i>Med Res Rev</i> , 21(3): 185-210, (2001).					
	AT 7	Wright, D.H., <i>et al.</i> , "Prostanoid Receptors: Ontogeny and Implications in Vascular Physiology," <i>Am J Physiol Regulatory Integrative Comp Physiol</i> , 281:R1343-R1360 (2001).					
	AU 7	Yu, V., <i>et al.</i> , "Differentiation of Human Neuroblastoma Cells: Marked Potentiation of Prostaglandin E-Stimulated Accumulation of Cyclic AMP by Retinoic Acid," <i>J Neurochem</i> , 51(6): 1892-1899 (1988).					
	AV 7	Zhang, Y., <i>et al.</i> , "Characterization of Murine Vasopressor and Vasodepressor Prostaglandin E2 Receptors," <i>Hypertension</i> , 35:1129-1134 (2000).					
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